

EXHIBIT 2

Supporting Statement for Paperwork Reduction Act Submissions
Suspicious Orders of Controlled Substances
OMB Approval #1117-NEW

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a new collection of information, Reporting and Recordkeeping Requirements Related to Suspicious Orders.

This information collection request is associated with DEA's "Suspicious Orders of Controlled Substances" rulemaking, RIN 1117-AB47. DEA is proposing to revise the regulations in order to implement the Preventing Drug Diversion Act of 2018 (PDDA) and, through the adoption of the two-option framework, to clarify the procedures a registrant must follow for orders received under suspicious circumstances (ORUSCs). The rulemaking requires all suspicious order reports to be made to DEA's centralized database with the required information, and all records of suspicious orders and ORUSCs to be prepared and maintained in accordance with DEA regulations, and must contain certain required information.

Part A. Justification

1. Necessity of Information:

DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1242 (1970), as amended (collectively, the CSA). 21 U.S.C. 801-971. The CSA imposed upon all registrants authorized to distribute controlled substances the duty to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. Furthermore, the CSA also contained provisions regarding suspicious orders. As codified in DEA regulations, these provisions require registrants to design and operate a system to disclose to the registrant suspicious orders of controlled substances, i.e., orders of unusual size, orders deviating from a normal pattern, and orders of unusual frequency. It also requires the registrant to "inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." 21 CFR 1301.74(b)

The "Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act" (SUPPORT Act) was signed into law on October 24, 2018. Pub. L. 115-271. The Preventing Drug Diversion Act of 2018 (PDDA) was contained within the SUPPORT Act, Sections 3291 and 3292. The PDDA required DEA to establish a centralized database for collecting reports of suspicious orders not later than 1 year from the date of the PDDA's enactment. Upon discovery of a suspicious order or series of orders, the PDDA required registrants to notify the DEA Administrator and the Special Agent in Charge of the

Division Office of DEA for the area in which the registrant is located or conducts business; alternatively, “[i]f a registrant reports suspicious order to the DEA centralized database ... the registrant shall be considered to have complied with the [notification] requirement ...” In essence, the PDDA replaced DEA Field Division Office reporting with centralized reporting to DEA Headquarters.

2. Needs and Uses:

As part of DEA’s implementation of the PDDA, a centralized database for collecting reports of suspicious orders will be established and the requirement for registrants to design and operate privacy-law-compliant suspicious order systems will be incorporated.

3. Use of Information Technology:

The PDDA required DEA to establish a centralized database for collecting reports of suspicious orders. Furthermore, upon discovery of a suspicious order, registrants are required to submit a suspicious order report to the DEA centralized database. This is not estimated to impose additional burden on registrants. The proposed rulemaking would require 100% of the suspicious orders reports to be submitted online.

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of information. The collection of this information is unique to DEA and is not duplicative.

5. Impact on Small Businesses or Entities:

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA’s evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For the purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. DEA has analyzed the economic impact if each provision of this rule and estimates the rule will have minimal economic impact on affected persons, including small entities.

6. Consequences of Less Frequent Collection:

Pursuant to the PDDA, registrants are required to submit a suspicious order report to DEA centralized database no later than seven calendar days after the order was received. If the collection were conducted less frequently, DEA would not have sufficient time to act and to promptly investigate potential diversion.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment is being solicited in the “Suspicious Orders of Controlled Substances” notice of proposed rulemaking (NPRM), published in the *Federal Register* at 85 FR 69282, on November 2, 2020. The NPRM has a 60-day comment period.

DEA meets regularly with affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift to respondents.

10. Assurance of Confidentiality:

Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. The information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information per 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

Below is an initial estimate of the estimate of hour burden and burden dollars. The estimated figures will be updated based on actuals for the next submission.

| Activity | Number of Annual Respondents | Number of Annual Responses | Average Time per Response (minutes) | Total Annual Hours |
|------------------|------------------------------|----------------------------|-------------------------------------|--------------------|
| Suspicious Order | 100 | 67,768 | 20 | 22,589 |
| ORUSC | | 271,072 | 15 | 67,768 |
| Total | 100 | 338,840 | N/A | 90,357 |

Burden hours:

Total annual respondents: 100

Frequency of response: 3,388.4 (as needed, calculated value)

Total annual responses: 338,840

Average burden per response (hour): 0.266667 (calculated)

Total annual burden (hours): 90,357

Burden dollars:

Loaded hourly wages: \$52.46¹

Burden dollars per response: \$13.99

Total burden dollars: \$4,740,372

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any additional start-up cost or capital expenditure or additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Costs to Federal Government:

There is no cost to the Federal government.

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

This is a new information collection request. Therefore, there is no change in burden.

16. Plans for Publication:

DEA will not publish the results of the information collected.

17. Expiration Date Approval:

DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

Part B. Statistical Methods

¹ Compliance Officer” (SOC 13-1041, 2018 Standard Occupational Classification, https://www.bls.gov/soc/2018/major_groups.htm), in the “Merchant Wholesalers, Nondurable Goods (4242 and 4246 only)” industry. The mean hourly wage for that position and industry according to the May 2018 National Occupational Employment and Wage Estimates United States (https://www.bls.gov/oes/current/oes_nat.htm) is \$36.76. Based on the BLS report, “Employer Costs for Employee Compensation—March 2019,” (ECEC) (<https://www.bls.gov/news.release/pdf/ecec.pdf>) an additional 42.7% load (for “private industry”) is added to the wage rate to account for benefits. $\$36.76 \times 1.427 = \52.46 .

DEA does not employ statistical methods in this information collection.